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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/202,047	12/07/98	ITOH	20-49211

002292 HM12/0822
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EXAMINER
HELMG, L

ART UNIT PAPER NUMBER
1042

DATE MAILED: 08/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/202,047	Applicant(s) ITOH ET AL.	
	Examiner Larry R. Helms	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/8/01.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 10, 11, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-15 are pending.
Claims 6-9 and 12-13 have been amended.
2. Claims 1-5, 10, 11, and 14-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in Paper No. 10.
3. Claims 6-9 and 12-13 are under examination.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
5. The following Office Action contains some NEW GROUNDS of rejections.

Specification

6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Rejections Withdrawn

7. The rejection of claims 6-9 and 12-13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.
8. The rejection of claims 7-8 and 12-13 under 35 U.S.C. 102(e) as being anticipated by Tsui et al (U.S. Patent 5,776,667, filed 6/6/95) is withdrawn in view of the amendments to the claims.

9. The rejection of claims 6-9 and 12-13 under 35 U.S.C. 102(b) as being anticipated by Boon et al (J. Exp. Med. 183:725-729, 3/1996, IDS #2) is withdrawn in view of the amendments to the claims.

10. The rejection of claims 6-9 and 12-13 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendments to the claims.

Response to Arguments

11. Claims 6-9 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakao et al (Cancer Res. 55:4248-4252, 10/1/95, IDS #2) is maintained.

The response filed 6/8/01 has been carefully considered but is deemed not to be persuasive. The response states that Applicants submit a declaration (paper #15 filed 6/28/01) by Dr. Itoh demonstrating that the claimed peptide antigens are distinct from those disclosed by Nakao et al. The declaration of Dr. Itoh has been carefully considered but is deemed not to be persuasive. The declaration states that the HPLC conditions set forth in Nakao et al gives peaks each containing plural peptides and the active peak (No. 23) corresponds to a mixture of peptides of unknown structure. In response to these arguments, the declaration does not state that the protein of Nakao et al in fraction number 23 is not that of amino acid sequence of SEQ ID NO:2 in the instant application. In addition, it is immaterial how the protein was obtained such as "expression cloning technique" because the claims are directed to the product not the method of isolation. In addition, the response fails to show a clear distinction between the claimed protein and the protein of Nakao et al as stated in the previous Office Action "Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antigen and the antigen of Nakao et al, the burden of proof is

upon the Applicants to show a distinction between the structural and functional characteristics of the claimed antigen and the antigen of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Moreover, the protein of Nakao et al is isolated (HPLC fractionation) and the protein in fraction 23 would inherently contain the amino acid sequence of SEQ ID NO:2 and be encoded by SEQ ID NO:1.

The following are some NEW GROUNDS of rejections

12. Claims 6-9 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6 has been amended to recite the limitation of "through intracellular processing" in the amendment filed 6/08/01. The amendment filed 6/08/01 does not state where in the specification support for the phrase is found. This is not persuasive because support needs to be found in the specification or the claims as originally filed. The term "decomposition" as defined by Stenesh in Dictionary of Biochemistry and Molecular Biology, second edition, page 118, 1989 is "the breakup of a chemical substance into two or more simpler substances" and the term "processing" is defined as "the series of chemical reactions whereby a newly synthesized polypeptide chain is converted to a functional protein" (see page 383). The specification does not support the definition of "possessing" and applicants are required to point to where the specification has support for this term or remove it from the claims. Alternatively, if

applicants agree with the definition of the term "decomposition" as taught by Stenesh, amending the claims to recite "intracellular decomposition" would be sufficient to obviate this rejection.

13. Claims 6-9 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 6-9 and 12-13 are indefinite for reciting "42⁰C, ____7" in claim 6 because it is unclear what is meant by the term. It is unclear if an additional term of phrase was meant to be added or needs to be added to the claim.

b. Claims 6-9 and 12-13 are indefinite for reciting "amino acid sequence shown in SEQ ID NO:1" and "nucleotide sequence shown in SEQ ID NO:2" because the exact meaning of the phrases are not clear. SEQ ID NO:1 is a nucleotide sequence and SEQ ID NO:2 is an amino acid sequence.

c. Claims 7 and 12 are indefinite for reciting "consisting of part of the protein" in claim 7 because the exact meaning of the phrase is unclear. What "part" of the protein is being claimed? Is "part" an amino acid, a carbon atom, etc?

Summary

14. No claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the

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Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

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